MAR 1 3 2009

K083263

510(k) Summary

Date

March 9, 2008

Contact

Rae Ann DeLay
Director, Quality, Regulatory and Health Care Compliance
SymCare Personalized Health Solutions, Inc.
200 Lawrence Drive
West Chester, PA 19380
Phone: (484) 686-4650
Email: rdelay@its.jnj.com.

Device Name

SymCare Diabetes Management Program

Common Name

Accessory to glucose test system

Classification

862.1345 – Glucose Test System – Class II
862.2100 – Calculator/Data Processing Module for Clinical Use – Class I

Predicate Devices

- MCT-Diabetes™ by MyCare Team Inc. cleared most recently via 510(k) K073699
- Think Positive (t+) Diabetes Management System by e-San Limited cleared most recently via 510(k) K061328

Device Description

The SymCare Diabetes Management Program (DMP) is an online tool that helps patients to manage their diabetes and communicate their blood glucose readings to their healthcare providers, healthcare providers manage their diabetes patient population, and insurance companies manage their diabetes patient and health care provider populations. The DMP enables a blood glucose meter to connect via a Bluetooth accessory, the Polymap Wireless Polytel® GMA Glucose Meter Accessory (GMA), to a cellular phone. Once the mobile phone has gathered the data from the meter, it transmits the data to a centralized repository database. The data is analyzed to recognize health patterns, show trends, and offer personalized health information.

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510(k) Summary, Continued

Indications

The SymCare Diabetes Management Program is intended for use in home settings to aid people with diabetes and healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Technological Characteristics

The SymCare Diabetes Management Program, like the predicate devices, is an internet-based software device.

Nonclinical Tests

Extensive software verification and validation testing was conducted and demonstrated compliance to requirements and design specifications.

Clinical Tests

A study to measure the usability of the SymCare DMP was conducted. The study demonstrated:

- comprehension of the study doctors, medical team members, and participants with the DMP,
- appropriate human factors related to the DMP, and
- ease of use of the DMP.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SymCare Personalized Health Solutions, Inc., concludes that the new device, the SymCare Diabetes Management Program, is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2009

Symcare Personalized Health Solutions, Inc .
c/o Rae Ann DeLay
Director, Quality, Regulatory & Health Care Compliance
200 Lawrence Drive
West Chester, PA 19380

Re: k083263
Trade/Device Name: Symcare Diabetes Management Program
Regulation Number: 21CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: February 27, 2009
Received: March 2, 2009

Dear Ms. DeLay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k083263

Device Name: SymCare Diabetes Management Program

Indication For Use:

The SymCare Diabetes Management Program is intended for use in home settings to aid people with diabetes and healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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